



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	AΠ	ORNEY DOCKET NO.	
08/7	32,408 12/09	7/96 REINMULLER	Ţ.	HUBR1099F	
· -		33M1/111 8		MINER	
	E AND LYNCH THIRD AVENUE		BL	BLACK, J	
	YORK, NY 10022		ART UNIT	PAPER NUMBER	
		`	33	08 8	
-			DATE MAILED:	11/18/97	

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No. 08/732,408

Applicant(s)

Examiner

John M. Black

Group Art Unit 3308

Reinmuller

X Responsive to communication(s) filed on Oct 22, 1996					
☐ This action is FINAL .					
Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.					
A shortened statutory period for response to this action is set to is longer, from the mailing date of this communication. Failure application to become abandoned. (35 U.S.C. § 133). Extension 37 CFR 1.136(a).	to respond within the period for response will cause the				
Disposition of Claims					
	is/are pending in the application.				
Of the above, claim(s)	is/are withdrawn from consideration.				
Claim(s)	is/are allowed.				
	is/are rejected.				
Claim(s)	is/are objected to.				
☐ Claims are subject to restriction or election requirement.					
Application Papers					
\square See the attached Notice of Draftsperson's Patent Drawing	g Review, PTO-948.				
☐ The drawing(s) filed on is/are object	ted to by the Examiner.				
☐ The proposed drawing correction, filed on	is 🗀 approved 🗀 disapproved.				
$\hfill\Box$ The specification is objected to by the Examiner.					
$\hfill\Box$ The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. § 119					
$oxed{oxed}$ Acknowledgement is made of a claim for foreign priority	under 35 U.S.C. § 119(a)-(d).				
· · · · · · · · · · · · · · · · · · ·	f the priority documents have been				
⊠ received.					
☐ received in Application No. (Series Code/Serial Nur	· · · · · · · · · · · · · · · · · · ·				
☐ received in this national stage application from the					
*Certified copies not received: Acknowledgement is made of a claim for domestic priorit	ty under 35 U.S.C. § 119(e)				
	., 4.100. 00 0.0.0. 5 1.10(0).				
Attachment(s) X Notice of References Cited, PTO-892					
	o(s). 8				
☐ Interview Summary, PTO-413	· · · · · · · · · · · · · · · · · · ·				
\square Notice of Draftsperson's Patent Drawing Review, PTO-94	18				
☐ Notice of Informal Patent Application, PTO-152					
SEE OFFICE ACTION ON T	THE FOLLOWING PAGES				

Art Unit:

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "thin foldable structural elements made of foil", "a covering", "tubular foils", "a foam structure" must be shown or the feature(s) cancelled from the claim(s). No new matter should be entered.

Specification

2. Content of Specification

- (a) <u>Title of the Invention</u>: The title of the invention should be placed at the top of the first page of the specification. It should be brief but technically accurate and descriptive, preferably from two to seven words. See 37 CFR 1.72(a).
- (b) <u>Cross-References to Related Applications</u>: See 37 CFR 1.78 and MPEP § 201.11.
- (c) <u>Statement as to rights to inventions made under Federally sponsored research and development (if any)</u>: See MPEP § 310.
- (d) <u>Background of the Invention</u>: The specification should set forth the Background of the Invention in two parts:
 - (1) <u>Field of the Invention</u>: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field".
 - (2) <u>Description of the Related Art</u>: A description of the related art known to the applicant and including, if applicable, references to specific related art

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and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

- (e) Summary of the Invention: A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (f) <u>Brief Description of the Drawing(s)</u>: A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (g) Description of the Preferred Embodiment(s): A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. This item may also be titled "Best Mode for Carrying Out the Invention." Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (h) <u>Claim(s)</u>: A claim may be typed with the various elements subdivided in paragraph form. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75.
- (i) <u>Abstract of the Disclosure</u>: A brief narrative of the disclosure as a whole in a single paragraph of 250 words or less on a separate page following the claims.

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Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
- 4. Claims 1, 2, 5, 7, 8, 11, 13, 17 and 18, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Ledergerber (EP 0 322 194).

Ledergerber discloses a prosthesis with compressive structures on the surface of the implant or in the interior of the implant (see Abstract). Foam is one example of a compressive structure. Compressive cells may contain a fluid, gas, gel or foam. The implant contains a covering and is expandable.

In re claim 1, the foil thickness of 10-200 um lacks criticality in the specification and is not deemed to be patentable subject matter.

In re claim 5, the structures appear tubular as best seen in Figs. 5a, 5b and 22.

In re claim 11, PTFEe is disclosed as a sheet covering. PTFEe is hydrophobic.

In re claim 13, see col. 10, lines 21-25.

In re claim 18, see col. 12, lines 51-58.

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5. Claims 1, 9 and 10, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg (5,116,387).

Berg teaches an injectable composition comprising polymeric bodies and a polysaccharide lubricant as set forth in the Abstract and claim 4.

In re claim 1, see paragraph 4 supra.

6. Claims 1, 2, 5-7, 9, 10 and 13, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Georgiade (5,219,360).

Georgiade discloses a mammary prosthesis comprising a coated elastomeric envelope enclosing a polysaccharide gel as set forth in the Abstract and col. 3, lines 20-25. Silicone rubber is a common elastomeric material for use as the envelope material.

In re claim 1, see paragraph 4 supra.

In re claim 6, hylan is hydrophilic.

7. Claims 1, 2, 5-8, 11 and 13-14, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi (5,206,298).

Kawaguchi teaches a contact lens made of polydimethylsiloxane where the surface is hydrophobic. The surface is modified with a covering to be hydrophilic. Applicant is referred to the Abstract, col. 1, lines 24-32, col. 2, lines 50-68 and col. 4, lines 40-56.

In re claim 1, see paragraph 4 supra.

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In re claim 7, it is common in the art to lubricate contact lenses with an aqueous liquid.

In re claim 8, Kawaguchi discloses that polydimethylsiloxane lenses are non-water swellable. Examiner is inferring from this statement that with a suitable liquid other than water, the lens would be swellable.

8. Claims 1, 2, 5-7, 11, 13 and 16, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman (4,348,329).

Chapman discloses a contact lens, a glass sheet and a Cuprophane membrane that are coated with a hydrophilic polymer film as set forth in col. 13, lines 5-15.

In re claim 1, see paragraph 4 supra.

In re claim 7, it is common in the art to lubricate contact lenses with an aqueous liquid.

In re claim 11, the surface prior to coating is hydrophobic.

9. Claims 1, 5-7, 11 and 13-15, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (4,657,553).

Taylor discloses an implant composing a hydrogel and an outer case. The hydrogel comprises a polysaccharide and/or protein and a hydrophilic polymer. The outer case is polydimethylsiloxane (col. 4, lines 37-40).

In re claim 1, see paragraph 4 supra.

In re claim 7, water is the lubricant (col. 3, lines 1-3).

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In re claim 11, the outer case is hydrophobic.

In re claim 15, the implant of Taylor is based on a polysaccharide (see Abstract).

Taylor discloses the shaping of the implant into various forms depending upon the need of the patient (see col. 3, lines 23-35).

10. Claims 1, 5-7 and 11-13, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hang-Fu (5,545,221).

Hang-Fu discloses an implant prosthesis comprised of a silicone-based envelope and a fillant material of adipose tissue, Wydase, Lidocaine/Epinephrine, water and saline as set forth in col. 3, lines 35-68.

In re claim 1, see paragraph 4 supra.

In re claim 11, silicone is hydrophobic.

In re claims 6-7, water and saline are hydrophilic.

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Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Shinoda et al.	5,194,473	Polyester compositions
Ersek et al.	5,258,028	Micro particle implants
Ersek et al.	5,336,263	Micro particle implants
Viegas et al.	5,376,693	Contact lens
Lewis et al.	5,534,609	Polysiloxane compositions

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John M. Black whose telephone number is (703) 305-7341.

JOHN G. WEISS

SUPERVISORY PATENT EXAMINER **GROUP 3300**

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November 7, 1997

JMB